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(71) Applicant: CHRISTIANSEN, Karen-Sofie, Administrator of the Estate of CHRISTIANSEN, Tor (deceased) [NO/NO]; Wergelandsveien 14, N-3600 Kongsberg (NO).

(72) Inventor: CHRISTIANSEN, Tor (deceased); Wergelandsveien 14, N-3600 Kongsberg (NO).

(74) Agent: LUND, Knud-Henry; Bryns Patentkontor A/S, P. Boks 9566, Egertorget, N-Oslo 1 (NO).

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(54) Title: BONE CEMENT

(57) Abstract

A bone cement for use in the cementing of protheses, especially protheses components for joint caps and bone marrow canals. The bone cement comprises polymethylmethacrylate, filler material in the form of particles of glass fiber or quartz having a particle size of 4 - 8 microns, and a silver ion-releasing material in the form of collodial silver (silver salt).

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BONE CEMENT

The invention relates to bone cement especially for cementing protheses, in particular protheses components for joint caps and bone marrow canals.

In 1965 a hip prothese was developed for use by elderly persons with fractures of the neck of the femur, because the conventional pins which had been used since 1938 had given such poor results. In 1970 this hip prothese was developed further into a so-called total protheses for use on patients with arthrosis, or arthritis of the hip joint owing to wear. With this type of protheses, one could reconstruct joints in which the cartilage had become worn down both in the cap of the joint and on the head of the joint. This protheses, named after its inventor, Tor Christiansen, has been patented.

A number of similar protheses have gradually come on the market. To improve the stability of the protheses component in the cap of the joint and the bone marrow canal, surgeons began to cement them in place with polymethylmethacrylate, a cement which dentists used earlier as a filling material for tooth cavities. Subsequent examinations of patients with hip protheses cemented with this cement, however, have shown that the cement has not been strong enough and that it also may be broken down in the organism by the enzyme catalase. Furhtermore, injuries to the surrounding bone have also been recorded, owing to the high curing temperature of the cement and to the cytotoxic liquid, the monomer, which is necessary for the curing process. The injuries to the bone tissue are probably the cause of the not-infrequent infections which often occur in the bone tissue many months later.

The object of the invention is to provide an improved cement which reduces or preferably eliminates the above detrimental effects.

Thus, the invention relates to a bone cement which is characterized by comprising polymethylmethacrylate, a filler material and a silver ion-releasing material.

The new cement is substantially stronger than the cement used previously, as may be seen from the table found below. The increased strength is obtained by the addition of filler in the form of particles of glass fiber or quartz having a particle size of 4 - 8 microns. To reduce or eliminate the fateful complication which a post-operative infection is, a silver ion-releasing material is also added to the cement, preferably in the form of colloidal silver having an express germicidal and anti-bacterial effect.

Colloidal silver solutions are combinations of insoluble forms of silver such as iodides, chlorides, oxides, etc., with protective colloids, usually organic. The insoluble forms of silver are precipitated in the presence of the protective colloids (for example, gelatins) in such manner that the particle size is very small and the particles do not settle but remain in suspension, and the resulting liquid has many of the advantages of an actual solution. These small particles of silver compounds act as reservoirs which release silver ions in a controlled manner and in small amounts; the actual concentration of silver ions will vary according to the nature of the silver compound present. As opposed to silver nitrate, for example, which has been used in medical applications, this colloidal silver has a so-called oligodynamic effect,

in that silver ions are continuously released over a long period of time. The silver ions will pass through the membrane of the bacteria and into the DNA molecule, in this way preventing propagation of the bacteria. The ratio of the three components of the bone cement mixture can vary as may be seen from the table found below, which shows the results of tests carried out by Det Norske Veritas.

When pure polymethylmethacrylate cement is cured at room temperature, the curing time is about 6 - 7 minutes and the curing temperature rises to about 90°C for a 10-mm thick layer. In the case of cement to which 25% glass fiber or quartz has been added, the curing time is 12-14 minutes under similar conditions. For cement with 50% quartz added, the curing time is 20-25 minutes and the curing temperature about 45°C. Since a curing time of as long as 20-25 minutes is impractical, the preferred bone cement comprises 65% polymethylmethacrylate with an addition of 30% quartz particles and 5% colloidal silver.

Qartz is preferred to glass fiber particles because the quartz particles are more irregular and thus provide a larger surface area than glass fiber particles. As mentioned above, the particle size for either quartz or glass fiber is between 4 and 8 microns. The larger surface area of the quartz particles may possibly help to make the cement less toxic by absorbing monomers, and one thereby also avoids the harmful high curing temperature.

Bending tests were carried out at Det Norske Veritas on test rods made of polymethylmethacrylate alone and on test rods made of the bone cement of the invention. The results were as follows:

BENDING TEST

Standard utilized	ISO/R 178
Test Rod dimensions	4 x 10 x 80 mm
Bending rate	2 mm/min
Storage	16 x t

Test Sample	Dimensions mm	Bending[x] module N/mm^2	Bending strength N/mm^2	Bend to break mm
A 1	3.9 x 10.0	2408	58.0	4.3
A 2	4.0 x 10.0	2688	66.0	4.2
B 1	4.0 x 10.0	5120	50.5	2.3
B 2	4.0 x 10.0	4941	47.7	2.2
D 1	4.0 x 10.0	4966	34.5	1.7
D 2	3.9 x 10.0	4815	35.0	1.7
E 1	4.0 x 10.0	6144	28.2	1.1
E 2	4.0 x 9.9	6723	27.8	1.0

[x]Bending module measured as secant module with a deformation equal to 10% of the thickness of the test sample.

A = pure cement (polymethylmethacrylate).

B = 70% by volume polymethylmethacrylate, 25% by volume glass fiber, 5% colloidal silver

D = 70% by volume polymethylmethacrylate, 25% by volume quartz, 5% colloidal silver

E = 50% by volume polymethylmethacrylate, 45% by volume quartz, 5% colloidal silver

In these tests, the bone cement "Simplex" was used for comparison purposes; the three types of bone cement used today in hip surgery all consist of polymethylmethacrylate.

The bone cement of the invention should preferably be used for the cementing of protheses, especially protheses components in joint caps and bone marrow canals, and the results obtained up to now have been very satisfactory.

Patent Claims.

1. A bone cement containing polymethylmethacrylate as a main component, characterized in that it also contains filler material in the form of particles of glass fiber or quartz having a particle size of 4 - 8 microns and a silver ion-releasing material in the form of colloidal silver (silver salt).

2. A bone cement according to claim 1, characterized by comprising

70 - 50% by volume polymethylmethacrylate
25 - 45% by volume quartz or glass fiber particles
5% by volume colloidal silver (silver salt).

3. A bone cement according to claim 2, characterized by comprising

65% by volume polymethylmethacrylate
30% by volume quartz particles
5% by volume colloidal silver (silver salt).

4. Utilization of the bone cement according to claims 1 - 3 for the cementing of protheses, especially protheses components in joint caps and bone marrow canals.

INTERNATIONAL SEARCH REPORT

International Application No PCT/NO81/00044

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC 3

A 61 F 1/00, A 61 K 31/78

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
IPC 2	A 61 K 5/00
IPC 3	A 61 F 1/00,1/03, A 61 K 6/00,31/74,31/765,31/78.../...

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [5]

SE, NO, DK, FI classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
Y	DE, A1, 2 906 413 (S.E.P.C.-S.A.R.L., SOCIÉTÉ D'EXPLOITATION DES PROCÉDÉS COATEX) 10 January 1980, pages 11-12	
Y	US, A, 3 932 627 (HARRY W MARGRAF) 13 January 1976	
A	DE, B2, 2 724 814 (KULZER & Co GmbH) 7 December 1978	
A	US, A, 2 347 567 (EDWARD J KRESSE) 25 April 1944	
A,P	WO, A1, 81/02667 (NATIONAL RESEARCH DEVELOPMENT CORPORATION) 1 October 1981	

* Special categories of cited documents: [15]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
1982-02-19	1982 -02- 26
International Searching Authority [1]	Signature of Authorized Officer [20]
Swedish Patent Office	Stefan E Lindén

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

II Fields Searched (cont)

IPC 3 C 08 L 33/10, 33/12

US Cl 3:1, 1.91; 424:78, 81

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [10]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers ... because they relate to subject matter [12] not required to be searched by this Authority, namely:

2. ☐ Claim numbers ..., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [11]

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.